



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FSIS-2018-0036]

Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

AGENCY: Food Safety and Inspection Service, USDA; Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) are hosting a joint public meeting to discuss the potential hazards, oversight considerations, and labeling of cell cultured food products derived from livestock and poultry tissue. FSIS and FDA officials will make presentations on their roles and responsibilities relative to the production and labeling of safe and wholesome food and their respective regulatory frameworks, including their inspection systems, as a basis for discussing what oversight framework might be most appropriate for cell cultured food products derived from livestock and poultry. Representatives of industry,

interested individuals, and other stakeholders are invited to participate in the meeting.

DATES: The public meeting will be held on Tuesday, October 23, 2018 from 8:30 a.m. to 4:00 p.m., and Wednesday, October 24, 2018, from 8:30 a.m. to 3:00 p.m. EDT. Submit either electronic or written comments on this public meeting by November 26, 2018.

ADDRESSES: The meeting will be held at the Jefferson Auditorium in the South Building, U.S. Department of Agriculture (USDA), 1400 Independence Avenue SW., Washington, DC 20250. Attendance is free. Non-USDA employees must enter through the Wing 5 entrance on Independence Avenue. The South Building is a Federal facility and attendees should plan to take adequate time to pass through the security screening system. Attendees must show a valid photo ID to enter the building.

FOR FURTHER INFORMATION CONTACT: Roxanne Smith, Director, Congressional and Public Affairs in the FSIS Office of Public Affairs and Consumer Education at (202) 720-4413 or roxanne.smith@fsis.usda.gov; as well as Juanita Yates, Public Affairs Specialist in the FDA Center for Food Safety

and Applied Nutrition at (240) 402-1731 or
Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Further information on this
meeting will be posted on the FSIS Web site at:

<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings>
and through the FSIS Constituent Update, and on the FDA Web
site at:

[https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConfer
ences/default.htm](https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm).

Background

FSIS is the public health agency responsible for
ensuring that meat, poultry, and egg products are safe,
wholesome, and accurately labeled. FDA has responsibility
for ensuring the safety of all other foods, including
seafood (except catfish) and game animals as well as
ensuring that the labels of these foods contain useful and
reliable information.

Animal cell culture food technology, as will be
discussed at the public meeting, refers to the controlled
growth of animal cells from livestock, poultry, fish, or
other animals, their subsequent differentiation into
various cell types, and their collection and processing

into food. Full tissue formation in culture is an active medical research area, as well as a strong focus of commercial interest for food applications. Many companies, both domestic and foreign, are actively developing products using this technology. Some of these products are being designed to have the same or similar compositional, nutritional, and organoleptic characteristics as traditional meat and poultry products. Once produced, the harvested cells could potentially be processed, packaged, and marketed in the same, or similar, manner as traditional meat and poultry products.

In the past several months, FSIS has received a significant amount of correspondence regarding the food products of animal cell culture technology. Much of the correspondence is in regard to a petition from the United States Cattlemen's Association to FSIS requesting, among other things, that FSIS prohibit products derived from livestock and manufactured using animal cell culture technology from being labeled or marketed as "beef" or "meat." The publication of this petition and related comments received by FSIS has brought significant attention to animal cell culture based food products. To date, FSIS

has received over 6,100 comments on this petition from industry trade associations; consumer advocacy groups; firms operating in the meat, poultry, and/or cell culture based food product markets; and consumers. In recent years, FDA also has been contacted by firms interested in developing foods that incorporate cultured animal cells from various species and has had a number of stakeholder engagements on this topic.

FDA, with USDA's participation, is developing technical questions related to cell cultured food products to put before FDA's Science Advisory Board on October 22, 2018 (notice will be published in an upcoming issue of the **Federal Register**). The intent of these questions is to support a process for identifying potential hazards, assessing risks, and establishing control measures appropriate to each risk for cell cultured food products. The dialogue with stakeholders at the joint public meeting that is the subject of this announcement will be informed by the FDA Science Board discussion, which will occur the previous day.

Topics for Discussion at the Joint Public Meeting

Given the high level of public interest, FSIS and FDA will be holding this joint public meeting in October to further discuss cell culture technology and provide the public with an opportunity to provide comments. The first day of the meeting will focus primarily on the potential hazards that need to be controlled for the safe production of animal cell cultured food products and oversight considerations by regulatory agencies. The second day of the meeting will focus on labeling considerations. General topics to be covered and discussed include:

- Potential hazards associated with the production of these products and a discussion on whether they are the same hazards as those associated with traditional meat and poultry products. What are the most significant sources of potential hazards for each and how are they similar and different?
- Strategies to ensure that all potential hazards are identified and appropriately controlled, including consideration of various factors relevant to determining oversight activities for these products, such as:

- o Is there an effective and efficient application of pre-market programs to ensure the safety of foods produced by animal cell culture?
- o What type and frequency of inspection will be appropriate for various stages of the manufacture of these products?
- o What type and frequency of inspection will be appropriate for products that combine cell cultured food products and other ingredients (e.g., multicomponent foods like soups, protein bars that contain cell cultured protein as an ingredient, or products that contain both traditional meat or poultry as well as cell cultured ingredients, including food products of animal cell culture derived from livestock and poultry tissue)?
- FSIS and FDA are actively working to reduce the duplicative and inefficient regulation of establishments and products under both agencies' jurisdiction. How could this be done for products of animal cell culture derived from livestock and poultry?

- What factors should be considered in the labeling of products of animal cell culture? Questions include:
 - o Should standards of identity or criteria for statements of identity be established for these products to ensure that product names are truthful, not misleading, and sufficiently differentiate cell cultured products from traditional products?
 - o Should the methods by which animal cell cultured products are produced (i.e., the culturing process be considered required information for purposes of labeling? If so, what factors should be considered in accurately describing the production methods?
 - o Should the source of the animal cells (i.e., the species from which the cell line was initiated) be considered required information for the purposes of labeling?
 - o What factors should be considered in potentially allowing health, safety, and other claims in the marketing of animal cell cultured products?

- o How should products containing both animal cell cultured products and traditional meat and poultry products be labeled?

Public Comments and Participation in Meetings

Registration:

To register for the public meeting, please visit the following website:

<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/meetings-archive/upcoming-meetings/meeting-registration-cell-culture-technology>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and voluntary and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting are requested to register by Friday, October 19, 2018, although non-registered attendees may still participate subject to availability. Early registration is recommended because seating is limited. Registrants will receive confirmation of their registration.

Accommodations for persons with disabilities:

To request accommodations due to a disability, please indicate any accommodations needed when registering. FSIS and FDA will provide sign language interpreters for this meeting.

Attendees from the media will also be asked to identify themselves during the registration process.

Public Comments: Oral Comments

Stakeholders will have an opportunity to provide oral comments during the public meeting. Due to the anticipated high level of interest in the opportunity to make public comments and the limited time available to do so, FSIS and FDA encourage participants to indicate when registering if they wish to give public comment during a public comment session and which topic(s) you wish to address. FSIS and FDA will do their best to accommodate all persons who wish to express an opinion. FSIS and FDA encourage persons and groups who have similar interests to consolidate their information for presentation by a single representative and request time for a joint presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. No commercial

or promotional material will be permitted to be presented or distributed at the public meeting. All requests to make oral presentations should be received by Friday, October 19, 2018.

Public Comments: Written Comments

Any stakeholder wishing to submit written comments prior to the meeting may do so, and may also submit comments after the meeting, using any of the following methods: Electronically: Go to <http://www.regulations.gov/> and follow the online instructions for submitting comments to docket FSIS-2018-0036; Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700; Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name (in this case FDA and FSIS) and docket number FSIS-2018-0036. Comments received in response to this docket will be made available for public inspection and posted without change, including

any personal information, to <http://www.regulations.gov/>.

Comments must be received by November 26, 2018.

On July 12, 2018, FDA held a public meeting on foods produced using animal cell culture technology. Comments received in response to that meeting will be reviewed jointly by FDA and FSIS. There is no need to resubmit comments already submitted to FDA.

Docket: For access to background documents or comments received, go to <https://www.regulations.gov> and insert docket number FSIS-2018-0036 into the "Search" box and follow the prompts; and/or call (202) 720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Question-and-Answer Periods:

Time has been allotted for audience questions after most presentations delivered during the meeting. Participants will have the opportunity to ask questions via a microphone in the auditorium.

Streaming Webcast of the Public Meeting:

This public meeting will also be webcast. Webcast participants are asked to preregister at

<https://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/meetings-archive/upcoming-meetings/meeting-registration-cell-culture-technology>.

Transcripts

The transcript of the proceedings from the public meeting will become part of the administrative record. As soon as the meeting transcripts are available, they will be accessible at <https://www.regulations.gov>; on the FSIS Web site at

<http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings>;

or on the FDA Web site at

<https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>. The transcripts may also be viewed at the FSIS Docket Room at the addressed listed above.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication online through the FSIS Web page located at:

<http://www.fsis.usda.gov/federal-register> and on the FDA Web site at:

<https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS Web page. Through the Web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex,

gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination, any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at: http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC on September 7, 2018

Paul Kiecker,
Acting Administrator.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018-19907 Filed: 9/10/2018 4:15 pm; Publication Date: 9/13/2018]